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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,516	07/21/2003	Fangcheng Gong	CL001195DIV2	9916

25748 7590 05/04/2004

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,516	GONG ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-23 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20, 21, drawn to a human synthase protein, classified in class 435, subclass 183.

II. Claims 4-6, 8-11, 22, 23, drawn to DNA, vectors, host cells encoding and expression of a human synthase protein, classified in class 536, subclass 23.2.

III. Claim 7, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

IV. Claim 3, drawn to an antibody that binds to a human synthase protein, classified in class 530, subclass 387.1.

V. Claim 12, drawn to a method for detecting the presence of a human synthase protein, classified in class 435, subclass 15.

VI. Claim 13, drawn to a method for detecting the presence of nucleic acid molecules encoding a human synthase, classified in class 436, subclass 94.

VII. Claims 14-15, drawn to a method for identifying a modulator of a human synthase protein, classified in class 436, subclass 63.

VIII. Claim 16, drawn to a method for identifying an agent that binds to a human synthase, classified in class 435, subclass 7.1.

IX. Claim 17, drawn to a pharmaceutical composition comprising an agent that binds to a human synthase, classified in class 424, subclass 9.1.

X. Claim 18, drawn to a method of treatment with an agent that binds to a human synthase, classified in class 424, subclass 9.2.

XI. Claim 19, drawn to a method for identifying a modulator of the expression of a human synthase, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I, II, III, and IV each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Group II comprises a nucleic acid sequence, the transgenic non-human animal in Group III is a multicellular organism whereas the proteins of Group I and IV each comprise an unrelated amino acid sequence. The DNA has other uses besides encoding the protein of Group I or being introduced in the transgenic animal of Group III, such as a hybridization probe or in gene therapy. The transgenic animal of Group III can have other uses such as in vivo testing besides manufacturing the protein of Group I. The protein from Group I can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the proteins of Group I and IV can be prepared by processes which are materially different from recombinant DNA expression of Group II or expression in the transgenic non-human animal of Group III, such as by chemical synthesis, or by isolation and purification from natural sources.

3. Inventions I and V, VI, X, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of Invention I is neither used nor made by the methods of Inventions V, VI, X, or XI.

4. Inventions I and II, III, or IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of Invention I, the DNA of Invention II, the transgenic non-human animal of Invention III, and the pharmaceutical composition of Invention IX are products that are distinct both physically and functionally, are not required one for the other, and have different uses and effects.

5. Inventions II and V, VII, VIII, or X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA of Invention II is neither used nor made by the methods of Inventions V, VII, VIII, or X.

6. Inventions III and V, VI, VII, VIII, X, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic non-human animal of Invention III is neither used nor made by the methods of Inventions V, VI, VII, VIII, X, or XI.

7. Inventions IV and VI, VII, VIII, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Invention IV is neither used nor made by the methods of Inventions VI, VII, VIII, or XI.

8. Inventions IX and V, VI, VII, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions V, VI, VII, VIII, X, and XI are not disclosed as capable of use together, comprise different steps, and produce different results.

9. Inventions IX and V, VI, VII, or XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the pharmaceutical composition of Invention IX is neither used nor made by the methods of Inventions V, VI, VII, or XI.

10. Inventions I and VII or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention I can be used in the distinct methods of Inventions VII and VIII, as well as to raise the antibodies of Invention IV.

11. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention II has other uses, such as in gene therapy or to make the protein of Invention I.

12. Inventions IV and V or X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IV can be used in the distinct methods of Inventions V and X.

13. The antibody of Group IV is related to the pharmaceutical composition of Group IX by virtue of being an agent capable of binding the human synthase of Group I. However, they are distinct inventions because the pharmaceutical composition of Group IX includes only those agents identified by the method of Group VIII which can be chemically and functionally unrelated to immunoglobulins, therefore, it does not require the antibody of Group IV. Further, the antibody of Group IV can be used in materially different and distinct processes such as the method of Group VI or the purification of the protein in Group I.

14. The pharmaceutical composition of Group IX is related to the method of Group VIII by virtue of containing an agent that can be identified with this method. However these are patentably distinct

inventions because the pharmaceutical composition of Group IX may neither be made by nor used in the method of Group VIII.

15. Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention X can use the antibody of Invention IV in a pharmaceutical composition of its own right.

16. Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant host cells of Invention I and native cells that normally express the synthase can be used in the method of Invention XI.

17. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

19. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

22. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
April 29, 2004

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